Food Safety Universe Database - A Semi-Quantitative Risk Assessment Tool

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Executive Summary

A method of systematically ranking food-safety-risks is needed to help prioritize the allocation of food safety resources. This document describes a Food Safety Universe Database (FSUDB), developed by the Ontario Ministry of Agriculture and Food (OMAF), that may be used as a semi-quantitative tool to rank food-safety-risks.

The FSUDB may be used to assess and rank food-safety-risks across various foods and hazards, at

various points along the food-chain. It assesses risk from a "societal" point-of-view, as influenced by differences in consumption patterns of various foods. It also assesses risk from a "per-serving" point-of-view, as influenced by differences in contamination rates of various foods. Furthermore, the FSUDB assesses risks of accidental contamination, and risks of deliberate contamination from acts of sabotage or terrorism.

The FSUDB does not replace fully quantitative mathematical models of risk. The risk-scores generated by system should not be taken too literally. They must be interpreted with caution. However, consistent trends in the relative ranking of risk-scores for different foods, hazards and situations, will be of value, as a source of information for the prioritization of food safety resources.

FSUDB data-entry, data-roll-up, out-put-interpretation and system-maintenance, all require specialized skills and a thorough understanding of the capabilities and limitations of the system. Furthermore, OMAF must demonstrate that access to data that are pertinent to food-system sabotage or terrorism, is restricted to only authorized individuals. Therefore, the FSUDB is maintained on a special restricted-access-computer-system with extra levels of security. Access is limited to only a few, specifically authorized, OMAF employees.

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1) Introduction, Background and Objective

Optimizing the use of finite resources is an important objective of food safety programs. Risk managers must strive to maximize (and equalize) the marginal return on investment across hazards and food types, in terms of reductions to food-safety-risks. To put it bluntly, tax-payers and consumers deserve the "biggest bang for their food-safety-buck". Unfortunately, this is not easily achieved given the complexity of the food system. Nevertheless, systematically assessing and ranking the risks to food safety is an essential step to achieving this objective.

Management Board, the Office of the Controller, and the Inspection Investigation and Enforcement Secretariat of the Government of Ontario have all called for the systematic application of principles of risk management to all programs within the Ontario Public Service, including food safety. The 2001 report of the Provincial Auditor specifically called for increased use of risk management in food safety programs. The Food Safety Policy Branch (FSPB) and the Food Inspection Branch (FIB) of the Ontario Ministry of Agriculture and Food (OMAF) are increasingly applying the principles of risk management to Ontario Food Safety System (OFSS) programs.

Food-safety-risk assessment involves systematically studying the likelihood and consequences of failures to food safety. Risk assessments may vary greatly in their level of detail. Assessments may range from: a) "back of the envelope" qualitative opinions, rating risks as "low, medium or high", through b) well documented, systematic, qualitative assessments of the likelihood and consequence components of defined risks, to c) semi-quantitative scoring and ranking systems, to d) complex, detailed, quantitative mathematical models that include Monte-Carlo simulation and quantification of uncertainty. The resources required for a risk assessment increase directly with the amount of detail included in the assessment. Text-based qualitative assessments are easier to produce, but less useful for ranking and prioritizing risks. Unfortunately, many resources are usually required to obtain appropriate data and to develop detailed mathematical models for full quantitative risk assessments. There is a need for a "middle ground" risk assessment tool that facilitates systematic ranking of many risks, without the detail and resources required to develop full mathematical models for each food and hazard. Such a tool was not available in the food safety literature.

The objective of this document is to describe a semi-quantitative, food-safety-risk-assessment tool that has been developed by the Ontario Ministry of Agriculture and Food (OMAF) to fill the need described above. This tool is to be used, in conjunction with other information, to help prioritize and optimize the allocation of food safety resources, under the influence of OMAF.

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2) System Design

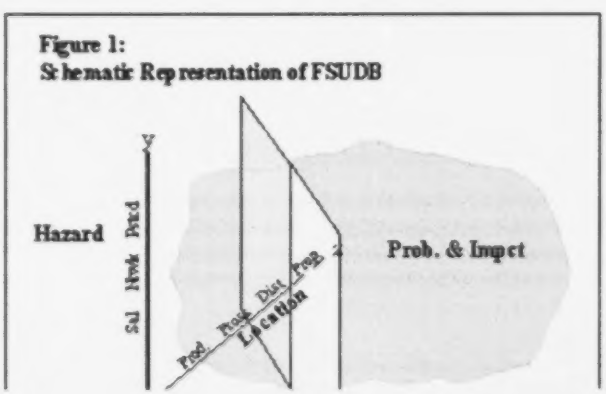
2.1) Summary of Concepts and Design Logic

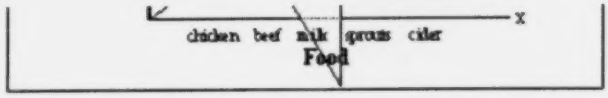
Risk is a function of the likelihood and consequences of an undesirable event occurring. As noted in the introduction, a systematic method of assigning scores for the likelihood and consequence components of risks from various hazards, in various foods, was needed to semi-quantitatively assess and rank risks to food safety.

Electronic databases offer advantages over word processing or spreadsheet files by facilitating systematic and repeated data capture, storage, searching, summarizing, counting, averaging, sorting, re-sorting, ranking and graphing. These functions are required to assess, prioritize and communicate food-safety-risks. Therefore, in response to the identified need, the following database program was developed in Microsoft AccessTM to capture and analyze likelihood and consequence food-safety-risk scores.

Different foods may be contaminated with various biological, chemical or physical hazards at different locations along the food-chain (from production to consumption), which may ultimately cause harm to the health of consumers. Each food-hazard-location-of-entry combination presents a different likelihood and consequence (risk) of harm. In theory, every possible combination of food-hazard-location-of-entry could be defined and assessed in terms of its likelihood and consequence. This theoretical complete data-set of all possible combinations could be thought of as the "universe" of food safety data. Therefore, the database designed to capture and analyze these data was named the Food Safety Universe Database (FSUDB).

Figure 1 is a schematic representation of the "universe" or cloud of likelihood and consequence data for every possible combination of food, hazard and location along the food-chain. Examples of different foods along the food dimension (x axis, Figure 1) include chicken, beef, milk, sprouts, cider, etc. In theory, every possible food product could be included along this dimension. Examples of different hazards along the hazard dimension (y axis) include Salmonella bacterial pathogens, Norwalk virus, pesticides, glass, etc. In theory, every possible food safety hazard could be considered along this dimension. Examples of different locations of hazard-entry along the food-chain (z axis), include production, processing, distribution, final food preparation etc. In theory, every possible location along the food-chain could be considered along this dimension. The plane through the cloud of data in Figure 1 schematically illustrates how risk-scores may be tallied-up within the electronic database, in a manner that is analogous to taking different slices through the data cloud. In Figure 1, the roll-up of data represented by the example slice (plane) through the cloud, would compare different food-safety-risk scores among different hazards that may enter milk during processing. Since the data are captured in semi-quantitative scores, they can be summarized in graphs or tables of ranked risk-scores. Also since the data are stored in a database, they can be summarized, tallied or ranked in essentially any manner analogous to taking any slice though the cloud of data entered in the system. This facilitates observing, comparing and ranking the recorded risk-data in essentially any way desired. This cannot be achieved if the data were stored in a word processing or spreadsheet file, whereas it can in a database.





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Explanation of abbreviations used in Figure 1:
Hazard: Sal = Salmonella, Nrwk = Norwalk virus, Pstcd = Pesticide
Location: Prod = production, Pross = processing, Dist = distribution, Prep = meal preparation
Prob = probability, Impct = impact

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2.2) Summary of Basic Data Capture and Basic Risk-scores

Table 1 summarizes the type of data captured in the database. First, the specific combination of food, hazard and location of hazard-entry are captured in each database record. Then, ordinal scores of 1 to 10 are captured to describe the probability (or likelihood) and impact (or consequence) components of the food-safety-risk. Scores are assigned for the risk believed to be presented to consumers by the specific hazard, entering the specific food, at the location along the food-chain described by each specific record in the database. The following provides an overview of the scoring and how it is used. More detailed definitions of the respective scores are provided in Section 3 of this document, where readers will note there are a few exceptions required for the basic 1 to 10 scoring system.

The probability (P) component of risk for each food-hazard-location combination is broken down into three sub-scores of 1 to 10 as follows:
Pa) scale of consumption is scored from 1 to 10 based on the amount of food consumed, the higher the scale of consumption, the higher the score;
Pb) the "proportion" of that food contaminated with that hazard at that location is scored from 1 to10 (see explanation of modification of this score in Section 3.2.2), the higher the proportion of contamination, the higher the score;
Pc) if contamination occurs then the "proportion" of that contaminated food that would lead to consumers being exposed to that hazard is scored 1 to 10 (see Section 3.2.3), the higher the proportion of exposure, the higher the score;
The impact (I) component of the risk for each food-hazard-location combination is also broken down into three sub-scores of 1 to 10 as follows:
Ia) if exposure occurs then of those consumers exposed to the hazard, the "proportion" that become ill is scored 1 to 10, the higher the proportion of exposed people that become sick, the higher the score;
Ib) if consumers become ill, then of those consumers that get sick, how sick they become is scored 1 to 10; the sicker people get, the higher the score;
Ic) difficulty to reduce or limit the impact; scored 1 to 10, the more difficult it is to limit impact, the higher the score. This may include increased scoring to account for secondary spread of infections.

The overall risk-score for each food-hazard-location combination is calculated by multiplying the six sub-scores together (i.e. Pa x Pb x Pc x Ia x Ib x Ic), so that potential risk-scores range from 1 to 1,000,000 as summarized in Table 1 below.

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Table 1: Summary of FSUDB Data Capture and Risk Scoring

Food-Hazard-Location Data:
Food: e.g. meat, chicken, fresh (ie 3 levels of detail)
Hazard: e .g. biological, bacteria, pathogenic *Salmonella*
Location: e.g. production (broiler chicken barns)
(i.e. location along food-chain that contamination occurred)

Probability Sub-Scores:
Pa) scale of consumption score (based on amount consumed per person per day) 1 - 10
Pb) of (Pa), the "proportion" contaminated with this hazard at this location; modified 1-10

Pc) of (Pb), the "proportion" that lead to consumer exposure to that hazard; 1 - 10

Impact Sub-Scores:
Ia) of those exposed (Pc), the "proportion" of consumers that become ill 1 - 10
(based on toxicity of chemicals, but inversely related in infective dose of organisms)
Ib) the severity of illness among consumers who become ill 1 -10
(based on acute and chronic health impacts)
Ic) difficulty to reduce or limit impact 1 - 10

Overall Risk-score: (for this food-hazard-location combination)
Risk "score" = Pa x Pb x Pc x Ia x Ib x Ic = range from 1 to 1,000,000
(see Section 3.2 for a description of situations where sub-scores <1 are used)

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Readers will note the word "proportion" has been placed in quotes above. This is because the word is not used in its simple mathematical sense, such that a score of "3" for sub-score "Pb" does not mean that 30% of the food is contaminated with that hazard at that point. Detailed definitions of each set of the ordinal sub-scores of 1 to 10 are provided in Section 3 of this document. It is recognized that ordinal scores of 1 to 10 do not represent the true range of variability that should be used in full mathematical models of risk, where values with ranges of many orders-of-magnitude would be more accurate. Therefore, although the intuitive 1 - 10 scoring system is used as much as possible, in some instances, a broader range of scores is allowed. See Section 3 for more detail.

Additional data are captured in the FSUDB in the following manner. Foods are coded according to type. Within each broad level of meat, dairy or plant origin foods, sub-classifications exist such as chicken, pork, beef etc. Within these sub-classifications, sub-sub-descriptions of the specific food exist such as fresh whole beef, fresh ground beef, ready-to-eat beef etc. This coding at different levels of detail facilitate roll-up of risk-scores for different groups of foods. Similarly, hazards are coded at different levels of detail starting with biological, chemical or physical classifications. Then sub-classifications such as bacteria, viruses or parasites within biological hazards, and then sub-sub-classification such as *Listeria monocytogenes*, pathogenic *Salmonella* or cytotoxic *E.coli* bacterial hazards etc. This coding facilitates roll-up of risk-scores for different types of hazards.

It should be noted that the location along the food-chain where a hazard enters, may or may not be the best location for the most effective and efficient control of that risk. For example, "downstream" pasteurization at dairies may be the most effective and efficient control for bacterial hazards that enter milk during on-farm production. Whereas "upstream" vaccination of cattle may be the most effective and efficient control for contamination of ground beef with cytotoxic *E.coli*.

Figure 2 illustrates the primary data-entry screen for the FSUDB. In general, most data are entered from pick-lists. The left-hand side of the screen prompts the user to enter different types of data. The middle part of the screen provides "pop-up pick-lists" from which the user picks appropriate available codes. The description of each code is provided in the pick-list and appears on the right side of the screen once a code has been selected. Pick-lists and descriptions are stored in tables in the background of this relational database. The database administrator controls any changes to the code tables.

The overall risk-score is calculated automatically by an algorithm programmed into the system. This algorithm may be changed or weighted differently by the database administrator if appropriate. Risk assessors' uncertainties about probability and impact sub-scores are also captured in uncertainty scores of 1 to 10. An uncertainty score of 1 represents no or negligible uncertainty. Whereas a score of 10, represents extreme uncertainty about probability or impact scores. These uncertainty scores are used in algorithms programmed into the database to place a type of confidence interval on the calculated risk-scores.

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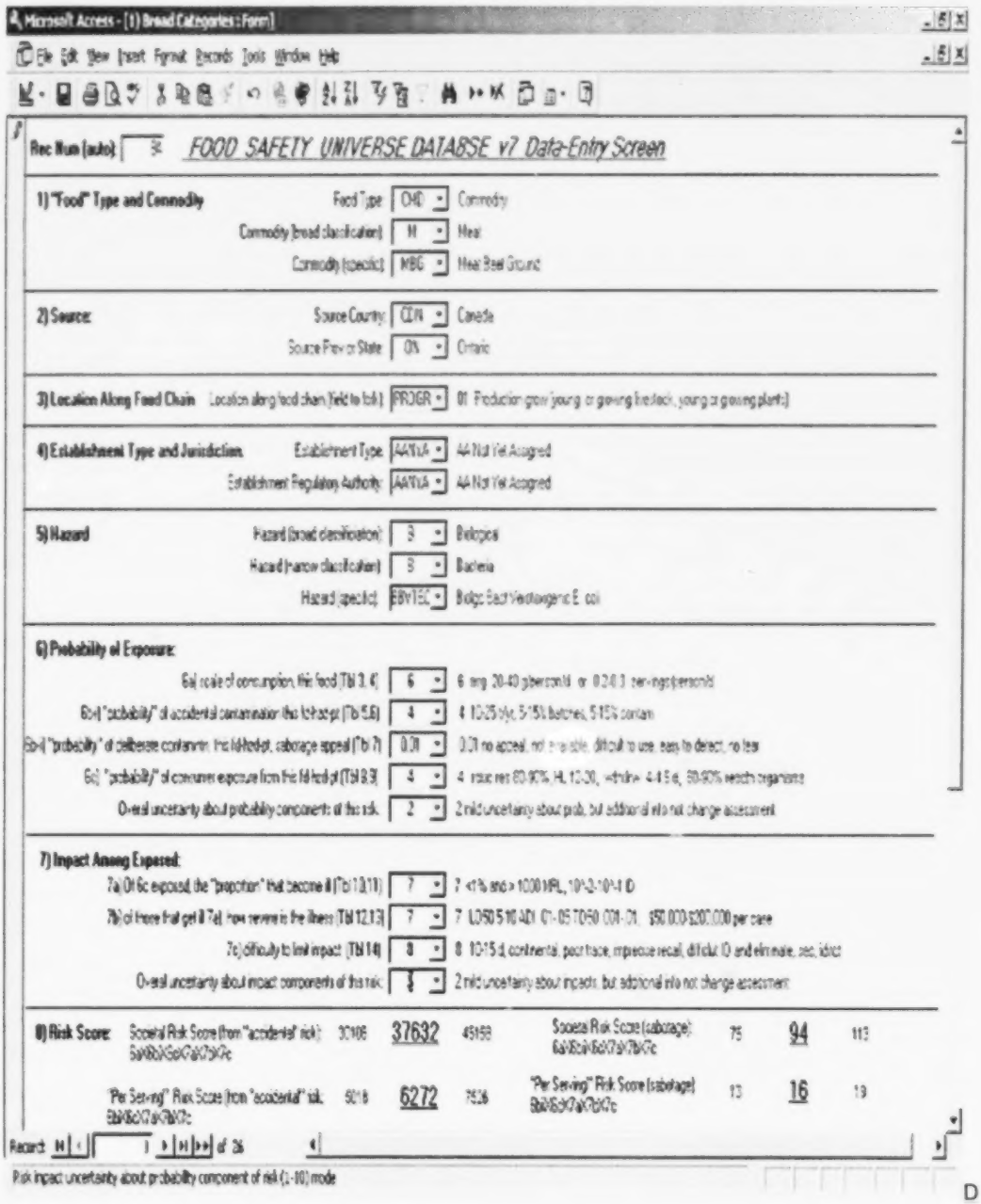
Figure 2: FSUDB Primary Screen


Microsoft Access - [1) Broad Categories : Form]
File Edit View Insert Format Records Tools Window Help
Rec Num (auto)
FOOD SAFETY UNIVERSE DATABSE v7 Data-Entry Screen
1) "Food" Type and Commodity
Food Type
Commodity
Commodity (broad classification)
Meat
Commodity (specific)
Meat Beef Ground
2) Source:
Source Country
Canada
Source Prov or State
Ontario
3) Location Along Food Chain
Location along food chain (Yelc to folk)
01 Production grow young or growing livestock, young or growing plants)
4) Establishment Type and Jurisdiction
Establishment Type
44 Not Yet Assigned
Establishment Regulatory Authority
44 Not Yet Assigned
5) Hazard
Hazard (broad classification)
Bacteria
Hazard (narrow classification)
Bacteria
Hazard (specific)
Bdgc Bact Verotoxigenic E. coli
6) Probability of Exposure:
6a) scale of consumption, this food (Tbl 3.4)
6 (eg. 20-40 gbercon/d) or 0.2-0.3 servings/person/d
6b-i) "probability" of accidental contamination this lot/batch/gp (Tb 5.6)
4 10-25 bty, 5-15% batches, 5-15% contain
6b-ii) "probability" of deliberate contamin. this lot/batch/et, sabotage appeal (Tb 7)
0.01 no appeal, not tmpting, difficult to use, easy to detect, no fear
6c) "probability" of consumer exposure from this lot/batch/gp (Tbl 8.3)
4 (eg. est 60-90% HL 10-30, <=hdn= 4-4.5 e, 80-90% reach organism)
Overall uncertainty about probability components of this risk.
2 mild uncertainty about prob, but additional info not change assessment
7) Impact Among Exposed:
7a) Of 6c exposed, the "proportion" that become ill (Tbl 12.11)
7 <1% and > 1000 /PL, 10^-2-10^-4 /D
7b) of those that get ill 7a), how severe is the illness (Tbl 12.13)
7 LOSS 5 10 ADI (1)-(5) TOSD (0)-(1), $50,000-$200,000 per case
7c) difficulty to limit impact (Tbl 14)
8 10-15 d, continental, poor trace, imprecise recall, difficult ID and eliminate, sec. idnct
Overall uncertainty about impact components of this risk.
2 mild uncertainty about impacts, but additional info not change assessment
8) Risk Score:
Societal Risk Score (from "accidental" risk):
30108
37632
45158
Societal Risk Score (sabotage):
75
94
113
"Per Serving" Risk Score (from "accidental" risk:
5018
6272
7526
"Per Serving" Risk Score (sabotage)
13
16
19
Record: 1 of 26
Risk impact uncertainty about probability component of risk (1-10) mode
D

See example Table 15.

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2.3) "Per-Food-Serving" Risk vs. Societal Risk

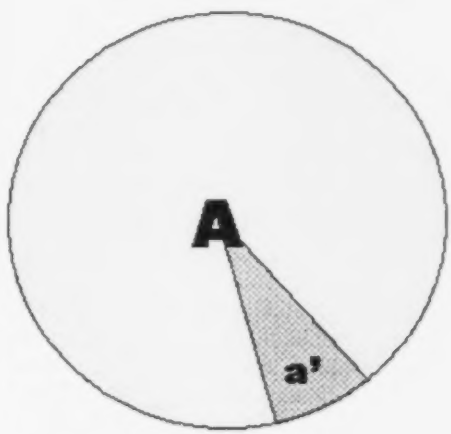
It is important that readers understand the concept of food-safety-risks on a "per-food-serving" basis vs. food-safety-risks to society that are based on the total number of people affected. These "per-serving" and "societal" risks are influenced by the scale of consumption and the proportion of food servings contaminated. The mathematics of these principles is explained below and summarized schematically in

Figure 3.

The scale-of-consumption (sub-score "Pa" in Table 1) has an important influence on the overall risk of a given food-hazard-location combination. For example, consider the scale-of-consumption of potatoes vs. caviar. Many more servings of potatoes are consumed in Ontario per year than caviar.

Now consider two different theoretical foods A and B. Assume 1,000,000 servings of food A are consumed each year, but only 1,000 servings of food B are consumed each year. Now assume that 0.1% of servings of food A were contaminated with hazard Z but 1% of servings of food B were contaminated with the same hazard Z. On a "per-serving" bases, the chance of being exposed to hazard Z is 10 times greater by eating food B vs. food A, but the total number of people exposed to hazard Z is 100 times greater from food A (0.001 contamination rate x 1,000,000 servings = 1000 exposures), than for food B (0.01 contamination rate x 1,000 = 10 exposures). If all other factors are equal in terms of the consequences of being exposed to hazard Z, regardless of whether that exposure was through food A or B, then the per-serving risk for food A is one tenth that for food B. However, because the scale of consumption for food A is 1000 times that of food B, the risk to society in terms of the number of cases of disease from hazard Z, is 100 times more from food A than from food B.

Figure 3: Schematic Representation of "Per-Serving" vs. Societal Risk



The "per-serving" risk of hazard Z (darker area) is less in food A than food B (ie a' is a smaller proportion of A then b' is of B), but the societal risk of Z in food A is greater than in food B because the number of cases in food A (area of a') is greater than in food B (area of b')

Food-safety-risk managers must keep both "per-serving" and "societal" risks in mind when designing food safety programs. Risks will be ranked differently depending on whether they are considered from a per-serving vs. a societal risk point-of-view. Including the scale-of-consumption (sub-score "Pa") in the calculation of overall risk-score (i.e. Pa x Pb x Pc x Ia x Ib x Ic = range of 1 to 1,000,000), results in a score from the risk-to-society point-of-view, because it is weighted by the scale-of-consumption. Whereas excluding the scale-of-consumption sub-score "Pa" from the calculation (i.e. Pb x Pc x Ia x Ib x Ic = range of 1 to 100,000), results in a score that is from the risk-per-serving point-of-view. It would be inappropriate to rank a mixture of scores some of which included sub-score "Pa" and some that did not. However, comparing one list of the relative ranking of risk-scores, all of which included sub-score "Pa", to a separate list of the relative ranking of the same hazard-food-location combinations, all of which did not include sub-score "Pa" in their calculations, is analogous to comparing the ranking of risks from a risk-to-society point-of-view to a risk-per-serving point-of-view. Risk managers will want to consider both points-of-view and both lists of ranked risk-scores (and how ranks differ), when they are designing and prioritizing food safety programs.

Figure 2 illustrates how FSUDB reports the "per-serving" and "societal" risk- scores for a given food-

hazard-location on the primary FSUDB screen. Risk-scores for any number of food-hazard-location combinations may also be sorted and presented in FSUDB print-out tables of risks ranked in descending order, or summarized n graphs.

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2.4) Risk to Different Segments of Society

Different segments of society often consume different food types in different amounts. For example, some consumers may rarely or never consume milk, whereas others may consume very large amounts of milk, especially per kg body weight. For a given chemical hazard the risk, when spread across all potential consumers, may be acceptably low. But for specific segments of society, such as young growing children, the risk may be unacceptably high, vs. the average risk across the entire population vs. the even lower risk among to some adults that only very rarely drink milk. This can be a result of the differences in consumption per-kg body-weight and different toxicity of the chemical in people at different stages of growth. The FSUDB can accommodate the different scores required for these different segments of society by maintaining separate data records for very specific food-hazard-location combinations, such as separate records where the food is defined as milk consumed by children less than 1 year of age vs. milk consumed by children 1 to 14 years etc.

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2.5) Accidental Contamination vs. Deliberate Contamination

Historically, food safety programs have focused on risks of accidental contamination. More recently, in addition to concern about accidental contamination, there is increased concern about deliberate contamination through acts of sabotage or terrorism. In the FSUDB, the proportion-contaminated sub-score "Pb", described in Section 2.2 and Table 1, attempts to score the likelihood or frequency of accidental contamination of the specific food by the specific hazard at the location in question. Thus the overall risk-scores (described above) attempt to score risks from accidental or unintended contamination.

If all things are equal, then the biological impact of the contamination of a specific food, with a specific amount of a specific hazard, at a specific location along the food-chain, is no different whether that hazard was introduced accidentally or deliberately. Therefore, all-things-being-equal, sub-scores "Pa" and "Pc" through "Ic" (Table 1) remain the same for the assessment of risks of accidental vs. deliberate contamination. The only difference lies in the likelihood-of-accidental vs. the likelihood-of-deliberate contamination by that hazard, of that food, at that location along the food-chain.

Therefore, two different sub-scores for "Pb" are required, identified as "Pb_i" for accidental contamination and "Pb_{ii}" for deliberate contamination. One caveat that must be kept in mind is that the amount of hazard used in a deliberate act of sabotage would likely be much greater than that which might enter by accidental contamination. Therefore, it may be prudent to create separate FSUDB records for accidental vs. deliberate contamination.

The detailed definitions of sub-score "Pb_i" for accidental contamination are described in Section 3.2.2 The societal accidental risk-score = Pa x Pb_i x Pc x Ia x Ib x Ic = range of 1 to 1,000,000. The per-serving accidental risk-score = Pb_i x Pc x Ia x Ib x Ic = range of 1 to 100,000.

Assigning a sub-score "Pb_{ii}" for deliberate contamination requires the risk assessor to think like a saboteur. He or she must think "If someone wanted to deliberately harm the system, what would they do that would be both easy to do and cause much harm?" Also, it is important to remember that acts-of-sabotage are not limited to large-scale systematic attacks by organized terrorists groups, but may also be initiated by disgruntled individuals. Competitors may even commit acts of industrial sabotage.

To conduct this type of sabotage-risk-assessment, analysts must have an excellent understanding of: a) the complexity of the agriculture and food systems, b) all major physical, biological and chemical hazards that could be deliberately introduced to these systems, c) the epidemiology of the potential impacts of

deliberately introduced hazards, at different or multiple points, within these complex systems, and d) the "sabotage appeal" (from a saboteur's point-of-view) of introducing different hazards, at different points, in terms of logistics, ease of introduction, the scale of the resultant negative impact and the panic or terror caused. Detailed definitions of sub-score "Pb_{ii}" are described in Section 3.

The societal sabotage-risk-score = Pa X Pb_{ii} X Pc X Ia X Ib X Ic = range of 1 to 1,000,000. The per-serving sabotage-risk-score = Pb_{ii} X Pc X Ia X Ib X Ic = range of 1 to 100,000. Figure 2 illustrates how FSUDB captures the accidental ($6b_i$) and sabotage ($6b_{ii}$) risk-scores for each food-hazard-location on the primary FSUDB screen.

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2.6) Additional Information Captured in the FSUDB

Information is also captured to allow comparison of risk-scores by food source, the type of establishment and the regulatory authority responsible for the food (see Figure 2).
Furthermore, notes on references, explanations of scoring and who assigned or changed scores, when and why, are also captured in the FSUDB (not shown in Figure 2). Similarly, notes on potential tools to control risks for that hazard-food-location combination may be recorded (not shown in Figure 2).

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3) Detailed Description of Probability and Impact Scoring

3.1) Basic Principles Used in Scoring

Table 2 summarizes the bases on which probability and impact scores are assigned to each food-hazard-location combination captured in the FSUDB. More detailed definitions of the scores are included in Sections 3.2 and 3.3. Table 15, provides an illustrative example of the application of the scoring definitions.

Briefly, the probability sub-scores (Pa, Pb and Pc) are based on the following factors:

Pa) The scale of consumption score ("Pa" in Table 1 and "6a" in Figure 2) is based on the amount of that food consumed per person per day. The scores are based on information reported in Canadian and American studies including: the "Nutrition Canada Survey", "The Compendium of Canadian Human Exposure Factors" and " Food Commonly Eaten the United States". This score depends on the food in question and the segment of society being considered. For biological hazards, it is based on the number of servings consumed, whereas for chemical hazards, it is based on the number of grams consumed per day. The more a food is consumed, the higher it is scored. Detailed data and ranges used for each scale of consumption score are defined in Section 3.2. Scoring is not linear.

Pb_i) The "proportion" "accidentally" contaminated score ("Pb_i" in Table 1 and "$6b_i$" in Figure 2) is influenced by the food, the hazard and the location being considered. This score can be modified to reflect situations where is it extremely unlikely that contamination with a particular hazard will occur at a particular point along the food-chain. The more likely the food in question is of being "newly" contaminated (or additionally contaminated), by the hazard, at this point (including increased contamination due to hazard growth or concentration), then the higher the score. Detailed data and ranges used for each "proportion" contaminated score are defined in Section 3.2. Scoring is not linear.

Pb_{ii}) The "proportion" contaminated by sabotage score ("Pb_{ii}" in Table 1 and "$6b_{ii}$" in Figure 2) is derived by the risk assessor's expert opinion of the "sabotage appeal" of contaminating that food with that hazard

at that point along the food-chain based on ease of logistics of acquisition and introduction of that hazard, to that food, at that point and the terror that such a deliberate introduction would cause. The greater the "sabotage appeal", the higher the score. Detailed data and ranges used for each proportion contaminated by sabotage score are defined in Section 3.2. Scoring was not linear.

Pc) The "proportion" of contamination that leads to exposure of consumers score ("Pc" in Table 1 and "6c" in Figure 2) is influenced by different factors for biological vs. chemical and physical hazards as well as the food in question and the location of contamination along the food-chain. In general, the likelihood of exposure to biological hazards is influenced significantly by the "location" of introduction along the food-chain relative to the "location" of any biological-hazard-inactivation-step (eg cooking, pickling) for that food.

For example bacterial contamination of milk before pasteurization is not scored as highly as similar contamination after pasteurization in terms of the proportion or likelihood of consumer exposure to such contamination. Whereas for chemical hazards this score is influenced by processing factors for the particular food, after the location of contamination, that would tend to reduce the concentration of the hazard, as well as chemical half life, pre-harvest intervals (pesticides) or withdrawal periods (drugs) and bio-accumulation. The greater the proportion of contaminated food that leads to actual exposure of consumers to the hazard, the higher the score. Detailed definitions are described in Section 3.2. Scoring is not linear.

Briefly, the impact sub-scores (Ia, Ib and Ic) are based on the following factors:

Ia) The "proportion" of consumers exposed that become ill score ("Ia" in Table 1 and "7a" in Figure 2) is approached in a similar manner for biological and chemical hazards. For biological hazards it is based on amount of exposure relative to the infective dose required to cause disease. Therefore in general, it is scored inversely with the number of organisms required to cause infection. More virulent biological organisms that require fewer organisms to cause infection are scored higher than less virulent hazards that require more organisms to cause infection. But in situations where the amount of contamination that is likely to exist by the time of exposure (eg situations where significant microbial growth or very heavy contamination is likely) then the amount of exposure relative to the infective dose is considered.

For chemical hazards, it is based on expected exposure relative to maximum residue limits (MRL) considering the food-hazard-location combination. Where appropriate, survey data illustrating the frequency of exposure to levels in excess of maximum residue limits is considered. The greater the exposure in multiples of MRL, the higher the impact score. Detailed definitions are described in Section 3.3. Scoring is not linear.

Ib) The score for the seriousness of illness among those that become ill ("Ib" in Table 1 and "7b" in Figure 2) is approached differently for biological vs. chemical hazards. For biological hazards it is based on per-case health-related-costs for different diseases. This includes direct health costs, days lost, chronic health impacts and statistical economic values of life for organisms that cause death. For chemical hazards it is based on toxicity data including acute and chronic impacts. The more serious the illness, the higher the score. Detailed definitions are described in Section 3.3. Scoring is not linear.

Ic) The score for difficulty to reduce or limit impact ("Ic" in Table 1 or "7c" in Figure 2) is influenced by several factors. Some examples include: i) the difficulty to detect contamination or an outbreak before it becomes widespread, ii) the length of the incubation period or time till adverse health effects are seen, iii) the distribution of the food in question relative to the location along the chain at which contamination occurred, iv) the difficulty in determining the food source of an outbreak through tracing, v) the difficulty of food recall and eliminating the source of contamination, vi) the amount of secondary spread of infection, and vii) the greater the indirect economic impacts. The greater the difficulty to limit the impact, the higher the score. Detailed definitions are described in Section 3.3. Scoring was not linear.

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Table 2: Summary of Scoring Principles

Sub-Score	Type of Information Used
Probability "Pa" or "6a" Scale of Consumption	Based on amount consumed of the respective food per person per day using data from Canadian and American studies; The greater the consumption, the higher the score
Probability "Pb_i" or "$6b_i$" Accidental Contamination	Based on frequency of chemical use and frequency of contamination with biological hazards. The greater the frequency and amounts, the higher the score
Probability "Pb_{ii}" or "$6b_{ii}$" Deliberate Contamination	Based on expert opinion of the sabotage appeal, influenced by logistical ease and expected terror; The greater the sabotage appeal, the higher the score
Probability "Pc" or "6c" Consumer Exposure	For biological hazards, based on likelihood of organism surviving to consumption, given the location of its introduction relative to inactivation steps (e.g. thermal or chemical treatments). For chemical hazards, based on processing steps that would reduce concentration, chemical half-life, pre-harvest intervals, drug withdrawal periods. The greater the likelihood of exposure, the higher the score.
Impact "Ia" or "7a" Consumer Illness	For biological hazards related to the amount relative to the infective-dose. For chemical hazards, related to the amount of exposure relative to maximum residue limits (MRLs) The greater the amount relative to infective-dose or MRL, the higher the score.
Impact "Ib" or "7b" Severity of Illness	For biological hazards, based on data of average health costs per case including treatment, hospitalization, lost days and statistical values of life. For chemical hazards based in toxicity including acute and chronic impacts The greater the health impacts, the higher the score.
Impact "Ic" or "7c" Difficulty to Limit Impact	Based on the difficulty to detect contamination, the distribution of the food, difficulty to determine and eliminate the source, the amount of secondary spread and indirect economic impacts. The greater the difficulty to limit impact, the higher the score.
Overall risk-score	Pa x Pb x Pc x Ia x Ib x Ic

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3.2) Detailed Scoring for the Probability Component of Risk

Tables 3 to 9, in Sections 3.2.1 to 3.2.3 below, describe definitions of sub-scores used to assess the probability component of food-safety-risks in the FSUDB. Table 15, provides an illustrative example of the application of the detailed probability sub-scores.

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3.2.1) Scale of Consumption (Pa and 6a)

Unfortunately, published data describing current consumption patterns in Ontario are limited. Therefore, information from the following reports was used including the: Nutrition Canada Study (based on data collected in 1970-1972), Compendium of Canadian Human Exposure Factors (1997 analyses) and the report on Foods Commonly Eaten in the United States 1994-1996 (by Smiciklas-Wright et al).

Data from the above publications was used by the authors of the FSUDB to define "scale of consumption" scores for foods. For chemical hazards the scale is based on average number of grams of each food, consumed per day, per person (Table 3). For biological hazards it is based on average number of servings of each food, consumed per day, per person (Table 4). These different approaches are needed for

chemical vs. biologic hazards because the likelihood of adverse effects from chemicals is more directly related to the amount of the chemical consumed. Whereas for biological hazards, the likelihood of adverse effects is less dependent on the actual number of organisms consumed, provided an infective dose is consumed in a serving.

For example, the average serving size of milk is much greater than the average serving size of spices. At equal concentrations, a consumer is exposed to much more chemical from one serving of milk than one serving of spice. Therefore, the amount consumed (g/day) of a particular food is more important than the number of servings consumed to achieve that amount. Whereas for biological hazards, the concentration of the hazard in the food and the amount consumed is less important. The number of contaminated servings consumed that are likely to have an infective dose is considered more important.

Table 3 is used to score the scale of consumption for chemical hazards. It illustrates the score assigned to grams of food consumed per day ("Pa" in Table 1 and "6a" in Figure 2) and provides several examples of such foods, based on data from consumption studies. Note that separate FSUDB records can be created for different segments of society based on grams-consumed-per-day per-kg-body-weight for that segment of the populations (eg young children). But for baseline FSUDB records, the score is based on an average consumption weighted by age groups in the overall population.

Table 3: Score definitions for scale-of-food-consumption, pertinent to chemical hazards ("Pa" and "6a")

[1] The higher the scale-of-consumption (g/person/day), the higher the score

[2] Score definitions were developed by the authors of the FSUDB to be used for internal consistency in the assessment and ranking of risks. See example Table 15.

Score[1]	Weighted average consumption (g/person/day) [2]	Example foods
1	<0.49	Raw potatoes, canned citrus fruit
2	0.5-1.9	Raisins, blueberries, shellfish (fresh or frozen), yogurt, lamb, broccoli
3	2-4.9	Organ meats (liver, kidney), canned fish, honey, celery, total peppers
4	5-9.9	Marine fish (fresh or frozen), cheese, cold cuts and luncheon meats, peaches
5	10-19.9	Lettuce, carrots, fresh tomatoes, cucumbers, rice, sugar (white), ice cream, butter, bread (whole wheat and rye), all cheese, raw apples, total fish
6	20-39.9	Milk (skim), beef (hamburger), pork, cereals, poultry, eggs, cake, pasta, citrus juice, citrus fruit (raw)
7	40-59.9	Soups, meat (canned), total tomatoes, total sugar
8	60-79.9	Bread (white), total beef
9	80-100	Alcoholic drinks, beer
10	>100	Fluid milk, potatoes, coffee, tea, soft drinks

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Table 4 is used to score scale-of-consumption for biological hazards. It defines scores for a range of average number of servings consumed per person per day ("Pa" in Table 1 and "6a" in Figure 2). Examples of products are included.

Table 4: Score definitions for scale-of-consumption, pertinent to biological hazards ("Pa" and "6a")

[1] The higher the scale-of-consumption (servings/person/day), the higher the score.
[2] Score definitions were developed by the authors of the FSUDB, based on Canadian and US data and expert opinion, to be used for internal consistency in the assessment and ranking of risks. See example Table 15.

Score[1]	Servings/person/day[2]	Applicable products
1	0-0.005	roe, unpasteurized apple cider
2	0.005-0.020	Shellfish (0.013), sprouts
3	0.020-0.05	fresh finfish (0.048), strawberries (0.021)
4	0.05-0.1	raw whole pork (0.08), melons (0.055)
5	0.1-0.2	raw tomatoes (0.14) whole beef (0.18), lettuce (0.19)
6	0.2-0.3	chicken/turkey (0.28), hamburger (0.25)
7	0.3-0.4	RTE meats including frankfurters (0.36), eggs (0.38)
8	0.4-0.5	Cheese (0.43)
9	0.5-0.6	
10	>0.6	milk (1.72)

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3.2.2) "Probability" of Contamination (Pb and 6b)

"Probability" of contamination is scored separately for "accidental" contamination (Pb_i and $6b_i$) vs. deliberate or sabotage contamination (Pb_{ii} and $6b_{ii}$). Note that "probability" of contamination for a given FSUDB record refers to "new" contamination occurring at that point along the food-chain, including: a) additional contamination introduced at that point along the food-chain, b) increased contamination resulting from microbial growth due to conditions favorable to growth at that point along the food-chain, or c) new contamination due to increased "cross contamination" at that point along the food-chain. It does not refer to contamination merely existing (still present in the food) at this point along the food-chain resulting from contamination that occurred "up-stream" along the food-chain. Slightly different factors were used to define probability-of-contamination- scores for chemical vs. biological hazards.

The score for probability of "accidental" chemical contamination (Pb_i and $6b_i$) includes contamination from routine use of approved agri-food chemicals, as well as accidental, unintended contamination by such chemicals (or unintended contamination by non-approved chemicals). It does not include deliberate contamination with the intent to do harm or cause sabotage (Pb_{ii} and $6b_{ii}$).

Table 5 illustrates the information used to derive a score for probability-of- accidental-contamination for chemical hazards, including routine approved use. It is based on knowledge of chemicals used or availability for agriculture and food processing practices, or chemicals to which items along the food-chain may be exposed.

Information on the amount of a particular herbicide, pesticide, fungicide, antibiotic, hormone, preservative, cleanser, disinfectant, lubricant etc used, frequency of use, point(s) along the food-chain such chemicals are normally used, economic incentive for illegal or off-label use, and likelihood of accidental or unintentional introduction of these, or non-agri-food chemicals, are considered. Also, if appropriate, the amount of "new" contamination from contamination that may occur from general exposure to the environment at that point of the food-chain, is considered (e.g. exposure to environmental pollutants during production).

For example, it might be known that a particular herbicide is routinely used during the early growing season for a particular list of crops. There is some economic incentive to use higher than label

concentrations. Although there is no economic advantage to use it at or near harvest, it may be accidentally applied. However, there essentially zero likelihood of accidental "new" contamination with this herbicide during processing, at the processing plant, because there is no reason whatsoever to have the herbicide present in the processing environment. Similarly given its cost, method of storage, appearance and method of application, it is extremely unlikely that it would be accidentally introduced to other commodities or any other points along the food-chain. Therefore, for the foods in which it is routinely used during crop production, the frequency of contamination score would be extremely high (eg. 10) for the FSUDB record(s) pertaining to that food (crop) and hazard, during production. It might be scored 2 or 3 at harvest. But for all other crops or foods, and even for this crop/food at other points along the food-chain it should receive a special score of 0.01 (ie. less than 1), as explained below.

Most scores used in the FSUDB were based on a simple, intuitive, 1 to 10 scoring system. Score-definitions are rarely linear, but to retain simplicity, most scores applied, ranged from 1 to 10. However, as noted in Section 2.2, a more accurate mathematical estimation of a risk-score would require use of more realistic non-linear score values and more complex modeling than the basic 1 to 10 system. Therefore, a few exceptions to the basic 1 to 10 scoring system had to be allowed within the FSUDB. These involved probability of contamination (Pb_i or $6b_i$ and Pb_{ii} or $6b_{ii}$) and probability of exposure (Pc or $6c_j$ scores.

These special scores are not meant to equal the actual probability values that would be used in a true mathematical model. They are only used to shift the overall score to more appropriate rankings and ranges, from those that would otherwise have been inappropriately achieved had the regular 1 to 10 sub-scoring been used.

For example, the probability-of-accidental-contamination that would normally be scored as 1, was replaced with a score of 0.01. This facilitated scoring of situations that are extremely unlikely or impossible to occur accidentally, such as contamination with a herbicide during processing or food preparation. If such contamination were to occur during food processing or food preparation, then the likelihood of exposure (Pc or 6c) would be very high (e.g. score 10). However, since the likelihood of "new" accidental contamination with a herbicide is so low during food processing or food preparation, it receives a special score of 0.01, which is less than 1. This in turn reduces the overall risk-score to an appropriately low value.

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Table 5: Score definitions for probability-of-chemical-contamination from accidental and routine use ("Pb_i" and "$6b_i$")

[1] The higher the likelihood of accidental (or routine use) contamination, the higher the score

[2] Score definitions were developed by the authors of the FSUDB to be used for internal consistency in the assessment and ranking of risks.

[3] Note that agricultural chemicals that are routinely used (eg some herbicides, some pesticides) are scored highly for the food and point along the food chain which they are routinely used. However, when used properly, following approved guidelines, the probability of consumer exposure to these chemicals is extremely low. This fact is accounted for in step Pc and 6c as defined in Table 8. See also an example application of the scoring in Table 15.

Score[1]	Usage/Presence of chemical [2,3] Used (tonnes/year) Treated "batches" (%) Environmental contamination (ppm)
0.01	Never intentionally used at this point, negligible probability of accidental contamination
0.1	<0.5 t/yr No reason or incentive to use, negligible-0.01% <0.01ppb
1	0.5-1 t/yr Used on 0.01-0.1% of batches 0.01-0.5ppb
2	1-5 t/yr Used on 0.1-1% of batches

	Used on 0.1-1% of batches 0.5-5ppb
3	5-10 t/yr Used on 1-5% of batches 5-50ppb
4	10-25 t/yr Used at least once on 5-15% of batches 50-250ppb
5	25-50 t/yr Used at least once on 15-30% of batches 250-500 ppb
6	50-75 t/yr Used at least once on 30-50% of batches 500-750 ppb
8	75-100 t/yr Used at least once on 50-90% of batches 750-1,000ppb
10	>100 t/yr Routinely used more than 2 X on the same batch, on > 90% of batches >1ppm

Table 6 illustrates the range of the proportion-of-servings-contaminated used to define the sub-score for accidental contamination ("Pb_i" in Table 1 and "$6b_i$" in Figure 2) for biological hazards. Examples of products are indicated. Note that the regular score of 1 is replaced with a score of 0.01 to allow more realistic weighting of situations where accidental contamination is extremely unlikely or essentially impossible. In a truly quantitative mathematical risk assessment model these sub-score weights would be based on actual estimated values. However, for this simplified semi-quantitative FSUDB system, sub-scores less than one, that will appropriately reduce the overall risk-score, are all that is needed.

Table 6: Score definitions for probability-of-accidental-contamination with a biological hazard ("Pb_i" and "$6b_i$")

[1] The higher the likelihood of accidental contamination, the higher the score.

[2] Score definitions were developed by the authors of the FSUDB to be used for internal consistency in the assessment and ranking of risks. See example Table 15.

Score1	Proportion2 accidentally contaminated	Examples of various food-hazard-location combinations observed to have different proportions of accidental contamination
0.01	Negligible	Hepatitis A virus/ beef/ production
0.1	Negl-0.01%	*E. coli* O157:H7/ beef/ consumer preparation
1	0.01-0.1%	*E. coli* O157:H7/ lettuce/ production
2	0.1-1%	*Salmonella*/ sprouts/ production
3	1-5%	*Listeria monocytogenes*/ RTE meats/ sec. Processing
4	5-15%	VTEC/ beef/ production
5	15-30%	*Salmonella*/ chicken/ processing
6	30-50%	*Listeria monocytogenes*/ smoked fish/ sec. Processing
8	50-90%	*Campylobacter*/ chicken/ processing
10	>90%	

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Table 7 illustrates score definitions used for sabotage appeal ("Pb_{ii}" in Table 1 and "$6b_{ii}$" in Figure 2). It is based on the average of four sub-sub-scores describing overall sabotage appeal. The same scoring system is used for biologic and chemical hazards. Again, because the probability of some hazard-food-location combinations being used for sabotage is so low, a sub-score of 0.01 was allowed to significantly reduce the overall risk-score for such situations.

Table 7: Score definitions for deliberate contamination with biological or chemical hazards ("Pb_{ii}" and "$6b_{ii}$")

Table 7 has been removed from this public version of the document for security reasons.

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3.2.3) "Probability" of Exposure (Pc or 6c)

This section of the FSUDB attempts to score the "probability" that consumers will be exposed to the hazard, if "new" contamination occurred at the location along the food-chain described by the FSUDB record, when that food is eaten normally at the end of the field-to-fork food-continuum. Similar to probability of contamination, some situations exist where the probability-of-exposure is so low (even if significant contamination has occurred "upstream" along the food-chain), that sub-scores of less than 1 for exposure had to be allowed. Again, the sub-scores are not directly proportional to their non-linear definitions as they would be in a true mathematical model, but they facilitate a broader spread of final risk-scores that is sufficient for this semi-quantitative system.

The approach used is slightly different for chemical vs. biological hazards, but the non-linear scores available for use are the same for chemical and biological hazards.

For chemical hazards, factors considered to influence the probability of exposure include: residue reduction by processing, half-life of the chemical, bio-accumulation and pre-harvest or withdrawal interval, as they relate to the chemical-food-location-of-entry being considered for the specific FSUDB record.

Table 8 summarizes information that is used to score probability-of-exposure to the chemical hazard in question, through normal consumption, resulting from new contamination of the food at the point being considered for the specific FSUDB record. Note the scores of less than 1 that are allowed, similar to Tables 5 and 6.

Table 8: Score definitions for probability-of-consumer-exposure to a chemical hazard, given contamination ("Pc" and "6c")

[1] The higher the likelihood of exposure, the higher the score.

[2] Score definitions were developed by the authors of the FSUDB to be used for internal consistency in the assessment and ranking of risks, based on the applicable information from the criteria described in the table. Note that for a routine agricultural chemical, that is used properly according to approved label instructions, it may score highly in Table 5 (Pb or 6b), but extremely low (<1) in Table 8 (6c or Pc). This is because when the agri-food chemical is used properly, there is little or no consumer exposure. See example in Table 15.

Score[1]	"processing"[2] factors reduce residue by %	Half life of chemical Days[2]	Bio-accumulation BCF [2] Log Kow	Pre-harvest Interval or Withdrawal Period (days) [2]
0.01	>99	<1	<100 <3	<0.25
0.1	>99	1-3	100-150 <3	<0.25
1	>99	3-5	150-200 3-3.25	0.25-0.5
2	95-99	5-8	200-300 3.25-3.5	0.5-1
3	90-95	8-12	300-500 3.5-4	1-2
4	80-90	12-20	500-750 4-4.5	2-5
5	60-80	20-40	750-1,000 4.5-5	5-10
6	40-60	40-60	1,000-2,000 5-5.5	10-20
8	5-40	60-100	2,000-5,000 5.5-6.5	20-40
10	<5	>100	>5,000 >6.5	>40

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Table 9 illustrates scoring for probability of consumer exposure to biological hazards ("Pc" in Table 1 and "6c" in Figure 2) as being influenced by the "location" of contamination along the food-chain relative to some sort of processing that would influence the level of exposure. Note the scores of less than 1 that are allowed.

Table 9: Score definitions for probability-of-consumer-exposure (Pc or 6c) for biological hazards

[1] The higher the likelihood of exposure, the higher the score

[2] Score definitions were developed by the authors of the FSUDB, to be used for internal consistency, in the assessment and ranking of risks, based on the applicable information. See example Table 15

Score1	Subsequent Contamination Reduction2	Contamination occurs prior to:	Examples of applicable products
0.01	> 5 log reduction	**Thermal processing** **Pasteurization** **Commercial cooking**	Canned shelf stable foods Fluid milk, cheese RTE meats
0.1	3-5 log reduction	**Commercial non-thermal processing:** smoking, fermentation, curing, long aging period	Certain smoked fish, fermented sausages, old cheeses
1	2-3 log reduction	**Commercial non-thermal processing:** smoking, fermentation, curing, aging period	Certain smoked fish, fermented sausages, aged cheeses (depending on the pathogen)

2	95%-99% reduction	**Consumer cooking:** pathogens not distributed internally and product has small surface area	Whole muscle pork cuts, whole beef, certain vegetables
3	90%-95% reduction	**Commercial non-thermal processing:** medium aging period **Long term exposure in the environment**	Certain mild cheeses (depending on the pathogen) Field crops, if contamination occurs in early production stages
4	80%- 90% reduction	**Consumer cooking:** pathogens distributed internally and consumer may prefer product undercooked; or product has large surface area	Hamburger, poultry
5	60%-80% reduction	**Washing** **Commercial non-thermal processing:** Minimal aging period	Easy to wash raw fruits/vegetable, eg cucumbers, peppers, tomatoes Certain semi-soft cheeses (depending on the pathogen)
6	40%-60% reduction	**Washing** **Commercial non-thermal processing:** Minimal aging period	Moderately difficult to wash raw fruits/vegetables Certain semi-soft cheeses (depending on the pathogen)
8	5%-40% reduction	**Washing** **Commercial non-thermal processing:** Minimal or no aging period	Hard to wash raw fruits/vegetables, eg lettuce, berries, cantaloupe, sprouts, herbs Certain semi-soft cheeses (depending on the pathogen)
10	< 5% reduction	**Consumption:** after last pathogen reduction step	-All foods contaminated at point of consumption -RTE meats and cheeses, contaminated post cooking/pasteurization

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3.3) Detailed Scoring for the Impact Component of Risk

Tables 10 to 14, in Sections 3.3.1 to 3.3.3 below, describe definitions of sub-scores used to assess the impact component of food-safety-risks in the FSUDB. Table 15 provides an illustrative example of the application of the detailed impact sub-scores.

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3.3.1) "Proportion" of Exposed Consumers That Become Ill (Ia or 7a)

The "proportion" of exposed consumers that become ill as a result of that exposure to that specific hazard, is influenced by the toxicity or virulence of the hazard and the amount to which the consumer is exposed relative to the critical amount required to cause illness.

Table 10 illustrates the scoring for impact in terms of consumers becoming ill given that they are exposed to chemical hazards ("Ia" in Table 1 and "7a" in Figure 2). It is based on exposure concentrations relative to maximum residue limits (MRLs). The greater the exposure beyond the MRL the greater the impact score.

Table 10: Score definitions for impact of exposure to chemical hazards (Ia or 7a)

[1] The greater the exposure beyond MRL, the higher the impact and the higher the score

[2] Score definitions were developed by the authors of the FSUDB to be used for internal consistency in the assessment and ranking of risks. See example Table 15.

Score1	Frequency of violations observed in surveys or expected concentrations relative to MRL2
1	<10 MRL
2	<1% and 10-100 MRL
3	1-10% and 10-100 MRL
4	<1% and 100-1,000 MRL
5	>10% and 10-100 MRL
6	1-10% and 100-1,000 MRL
7	<1% and >1,000 MRL
8	>10% and 100-1,000 MRL
9	1-10% and >1,000 MRL
10	>10% and >1,000 MRL

Table 11 illustrates the scoring for impact in terms of consumers becoming ill given that they are exposed to biological hazards ("Ia" in Table 1 and "7a" in Figure 2). It is based on data available describing the dose required to cause infection and consideration of the fraction of that infective dose, to which consumers are likely to be exposed given the situation described by hazard, food, point of contamination triad of the FSUDB record being completed.

Table 11: Score definitions for impact of exposure to biological hazards (Ia or 7a)

[1] Biological impact is influenced by exposure to an infectious dose. Some pathogens require fewer organisms to exceed an infectious dose,. The greater the fraction of infectious dose consumed, the greater the impact of exposure, the higher the score.
[2] Score definitions were developed by the authors of the FSUDB to be used for internal consistency in the assessment and ranking of risks.
[3] Examples of different organisms with increasing likelihood of being present at their infectious dose, even if minimal concentrations are present. Organisms with lower infectious doses are scored higher because the are more likely to have an impact by causing illness, even at a low concentration. See example Table 15.

Score[1]	Fraction of the infectious dose at point of consumption[2]	Examples of scores for different pathogens, assuming pathogen is present in food at minimal concentration at point of consumption[3]
1	$<1/10^8$	*E. coli* enterotoxigenic, *Bacillus cereus*
2	$1/10^6$ -$1/10^8$	*Salmonella* spp.[1], *Clostridium perfringens*, *Yersinia enterocolitica*, Streptococcus, *E. coli* other diarrheogenic, *Vibrio cholerae*, *Listeria monocytogenes*
3	$1/10^5$-$1/10^6$	*Staphylococcus aureus*
4	$1/10^4$-$1/10^5$	
5	$1/10^3$-$1/10^4$	
6	0.01-0.001	*Cryptosporidium parvum*, *Cyclospora cayetanensis*, *Trichnella spiralis*, *Campylobacter* spp., *Vibrio vulnificus*

7	0.1-0.01	VTEC, *Shigella* spp., *Toxoplasma gondii*, *Giardia lamblia*, Hepatitis A, Rotavirus, Astrovirus
8	1-0.1	Norwalk virus group
9	2-1	
10	>2	

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3.3.2) Severity of Illness (Ib or 7b)

Table 12 illustrates scoring for impact in terms of the severity of illness from exposure to chemical hazards ("Ib" in Table 1 and "7b" in Figure 2). It is based on acute and chronic toxicity data.

Table 12: Score definitions for impact of chemical hazards in terms of severity of illness (Ib or 7b).

[1] The greater the severity of illness among cases (including death), based on the toxicity of the chemical, the higher the score.
[2] Score definitions were developed by the authors of the FSUDB to be used for internal consistency in the assessment and ranking of risks, in this case based on an average of applicable sub-sub-scores. See example Table 15.

Score[1]	Oral Lethal Dose 50[2], LD50 (mg/kg)	Oral Reference Dose/ Acceptable/Tolerable Daily Intake[2], RfD/ADI/TDI (mg/kg/day)	Cancer potency, Factor q1, TD50 (mg/kg/day), IARC Classification[2]
1	>5,000	> =10	< =0.0001 >=1000 **4** = probable not carcinogen
2	500-5,000	5-10	0.0001-0.001 100-1000 **3** = not classifiable as carcinogen
3	100-500	1-5	0.001-0.01 10-100
4	50-100	0.5-1	0.01-0.1 1-10
5	25-50	0.1-0.5	0.1-1 0.1-1
6	10-25	0.05-0.1	1-10 0.01-0.1
7	5-10	0.01-0.05	10-100 0.001-0.01
8	2-5	0.005-0.01	100-1000 0.001-0.01 **2B** = possible human carcinogen
9	0.5-2	0.001-0.005	1000-10,000 0.001-0.01 **2A** = probable human carcinogen
10	<0.5	< = 0.001	>=10,000 <=0.001

			1 = known human carcinogen

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Table 13 illustrates scoring for impact in terms of severity of illness among consumers that become ill subsequent to exposure to biologic hazards ("Ib" in Table 1 and "7b" in Figure 2). It is based on data describing the average cost per case for specific illnesses including treatment, hospitalization, lost time, statistical value of life..

Table 13: Score definitions for impact of biological hazards in terms of cost per case (Ib or 7b)

[1] The greater the severity of illness among cases, the higher the score. See example Table 15.

[2] Score definitions were developed by the authors of the FSUDB to be used for internal consistency in the assessment and ranking of risks, in this case based on estimated health related costs per case and case mortality rates. Disability adjusted life years (DALY's) were used for comparison of impacts of chemical hazards. Note that DALY's are a relatively new method of measuring disease impacts of different hazards. Health Canada (and other regulators) are currently (2003) estimating DALYs for various hazards.

Score1	Health-related cost per case (Canadian $)2	Examples of pathogens (case mortality rate;DALYs)2
1	Impact unknown or unproven	Mycobacterium paraturberculosis
2	<1,200	Streptococcus (0%; 0.0033), *Bacillus cereus* (0%; 0.0033), Astrovirus (0%; 0.0033), Rotavirus (0%; 0.0033), *Yersinia enterocolitica* (0%; 0.0033), *E. coli* enterotoxigenic (0.0007%; 0.0034), *E. coli* other diarrheogenic (0.0007%; 0.0034), *Staphylococcus aureus* (0.0012%; 0.0035), Norwalk virus group (0.0018%; 0.0035), *Giardia lamblia* (0.002%; 0.0036), *Clostridium perfringens* (0.0029%; 0.0037), *Cyclospora cayetanensis* (0.0034%; 0.0037)
3	1,200-2,500	*Campylobacter* spp. (0.0064%; 0.0043), *Shigella* spp. (0.014%; 0.0050)
4	2,500-5,000	*Salmonella* nontyphoidal (0.029%; 0.0067)
5	5,000-20,000	*Cryptosporidium parvum* (0.045%; 0.0086)
6	20,000-50,000	*Vibrio* other (0.33%; 0.042), *Trichinella spiralis* (0.39%; 0.049), *Toxoplasma gondii* (0.44%; 0.054), Hepatitis A (0.45%; 0.056), *Salmonella typhi* (0.53%; 0.066)
7	50,000-200,000	VTEC (0.15%; 0.023), *Vibrio cholerae* (0.78%; 0.094), *Brucella* spp. (0.94%; 0.11)
8	200,000-1,000,000	
9	>1,000,000; <50% mortality	Botulism (10.3%; 1.20), *Listeria monocytogenes* (31.7%; 3.72)
10	>50% mortality regardless of cost/case	*Vibrio vulnificus* (51.0%; 5.98)

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3.3.3) Difficulty to Limit Impact (Ic or 7c)

Table 14 illustrates sub-sub scores that are rolled-up to obtain a score for difficulty to limit impact for chemical or biologic hazards ("Ic" in Table 1 or "7c" in Figure 2).

Table 14: Score definitions for difficulty to reduce impact (Ic or 7C) of chemical and biologic hazards

[1] The greater the difficulty to limit impact, the higher the score

[2] Score definitions were developed by the authors of the FSUDB to be used for internal consistency in the assessment and ranking of risks, in this case based on average of applicable sub-sub-scores for time to realize problem, extent of required recall, difficulty to eliminate, presence of secondary spread and/or indirect economic impacts. See example Table 15.

Score[1]	Time to realization of problem in days[2]	Extent of required recall[2] Difficulty to eliminate source of contamination[2]	Secondary spread (bio hzrds)[2] Indirect economic impacts[2]
1	0.5	Small defined source no recall Easy to ID and eliminate source	No secondary infection No indirect economic impacts
2	1	Local distrb small recall Easy to ID and eliminate source	No secondary infection No indirect economic impacts
3	1-2	Regional distrb moderate recall Easy to ID and eliminate source	No secondary infection No indirect economic impacts
4	3	Provincial distrp Mod-large rcall Can ID source with investigation and eliminate at some cost	No secondary infection No indirect economic impacts
5	4	2 - 3 Prov distrb Can ID source with investigation and eliminate at some cost	No secondary infection No indirect economic impacts
6	5	National distrb national recall Can ID source with investigation and eliminate at some cost	Some secondary spread of infection Some indirect economic impacts
7	5- 10	North American but good tracing specific product recall Can ID source with investigation & eliminate at some cost	Some secondary spread of infection Some indirect economic impacts
8	10 - 15	Trans continental But good tracing specific product recall Very difficulty to ID source & very difficult to eliminate source	Some secondary spread of infection Some indirect economic impacts
9	15 - 30	North American but poor tracing imprecise recall Very difficulty to ID source & very difficult to eliminate source	Significant secondary infection Significant indirect economic impacts
10	> 30	Trans continental but poor tracing imprecise recall Very difficulty to ID source and very difficult to eliminate source	Significant secondary infection Significant indirect economic impacts

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4) Illustrative Examples

Table 15 illustrates three examples of the application of the sub-score definitions described in Tables 3 through 14 and the subsequent derivation of FSUDB risk-scores for three different scenarios.

Table 15: Derivation of FSUDB risk-scores for three different scenarios

Description	Definition Table	Scenario 1	Scenario 2	Scenario 3
Food	-	**ground beef**	**chicken muscle**	**lettuce**
Hazard	-	**Verotoxic *E.coli***	**Metals and elements, Arsenic**	**Pesticide, Cypermethrin**
Location of hazard entry	-	**Animal production on farm**	**Animal production on farm**	**Vegetable production on farm**
Pa or 6a Scale of consumption	Chem Hz Tbl 3		**6**	**5**
Pa or 6a Scale of consumption	Bio Hz Tbl 4	**6**		
Pb^{i} or $6b^{i}$ Accidental contamination	Chem Hz Tbl 5		**3**	**4**
Pb^{i} or $6b^{i}$ Accidental contamination	Bio Hz Tbl 6	**4**		
Pb^{ii} or $6b^{ii}$ Deliberate contamination at this point	Avg of sub- sub-scres Tbl 7 **or** override	low appeal at animal production override **0.01**	low appeal at animal production override **0.01**	low appeal at vegetable production override **0.01**
Pc or 6c Exposure	Chem Tbl 8 Prces Redctn		10	6
	Chem Tbl 8 half life		6	5
	Chem Tbl 8 bio accum		0.01	4
	Chem Tbl 8 Intvl Wthdrwl		1	6
Pc or 6c Chem score	Avg of available Chem		(10+6+0.1+1)/4 4.25=**4**	(6+5+4+6)/4= 5.25=**5**
Pc or 6c Bio score	From Tbl 9	**4**		
Ia or 7a Illness among exposed	Chem Tbl 10 MRLs		**1**	**3**
Ia or 7a Bio score	From Tbl 11	**7**		
Ib or 7b Severity	Chem Tbl 12 Oral LD50		10	4
	Chem Tbl 12 RFD/ADI/TDI		10	6
	Chem Tbl 12		8	8

	Chem Tbl 12 Cancer		0	0
Ib or 7b Chem score	Avg available sub-sub-scores		(10+10+8)/3 9.3=**9**	(4+6+8)/3 =**6**
Ib or 7b Bio score	From Tbl 13	**7**		
Ic or 7c Difficulty to reduce impact	Tbl 14 time to realize	9	6	6
	Tbl 14 Extent of recall & difficulty	6	6	5
	Tbl 14 2^0 sprd, indirct impct	8	2	2
Ic or 7c score	Avg of sub-sub - scores	(9+6+8)/3= 7.6=**8**	(6+6+2)/3= 4.6=**5**	(6+5+2)/3= 4.3=**4**
Risk-score Societal accidental Max 1,000,000	$Pax Pb^{i} x Pcx$ Iax Ibx Ic	6x4x4x7x7x8= **37,632**	6x3x4x1x9x5= **3,240**	5x4x5x3x6x4= **7,200**
Risk-score Per-serving accidental Max 100,000	$Pb^{i} x Pcx$ Iax Ibx Ic	4x4x7x7x8= **6,272**	3x4x1x9x5= **540**	4x5x3x6x4= **1440**
Risk-score Societal deliberate Max 1,000,000	$Pax Pb^{ii} x Pcx$ Iax Ibx Ic	6x.01x4x7x7x8= **94**	6x.01x4x1x9x5= **10.8**	5x.01x5x3x6x4= **18**
Risk-score Per-serving deliberate Max 100,000	$Pb^{ii} x Pcx$ Iax Ibx Ic	0.01x4x1x9x5= **16**	0.01x4x1x9x5= **1.8**	0.01x5x3x6x4= **3.6**

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5) Interpretation of Risk-Scores and System Maintenance

The risk-scores generated by FSUDB should be interpreted with caution. Their calculated values should not be taken too literally. The score definitions and the resultant risk scores are not linear. However, consistent trends in the relative ranking of risk-scores will help to prioritize and optimize the allocation of food safety resources.

As noted previously, the location along the food-chain where a hazard enters, may or may not be the best location for the most effective and efficient control of that risk. Therefore, food-hazard-location combinations with high risk-scores illustrate combinations that result in high risks, but the best location of risk control may or may not be at that point along the food chain.

The flexibility of the FSUDB to average and sum scores across hazards, foods and locations along the food-chain, or combinations thereof, can help decision-makers to assess food-safety-risks from different perspectives. Again, scores should be interpreted with caution. However, consistent trends in ranking are likely significant. Analysts must be aware of the number and type of records used in FSUDB averages and sums so as to ensure a biased "view" is not taken by virtue of differences in the number of different types of records included in the roll-ups.

FSUDB data-entry, data-roll-up, out-put-interpretation and system-maintenance, all require specialized skills and a thorough understanding of the capabilities and limitations of the system. Failure to maintain and use the FSUDB appropriately will generate inappropriate and potentially misleading results.

Furthermore, OMAF must demonstrate that access to data, that are pertinent to food-system sabotage or terrorism, is limited to authorized individuals only. Therefore, the FSUDB is maintained on a special restricted-access-computer-system with extra levels of security. Direct access to the system and 'write' authority is limited to only a few, specifically authorized, OMAF employees. Data entry and requests for updates, printouts and graphs are directed through these individuals.

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